REMARKS

Claim 10 has been canceled. The 35 U.S.C. § 112, second paragraph, rejection is now moot.

Claims 1, 4, 7-11 and 13-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by EP 0399918 ("EP '918"). Reconsideration and removal of the 35 U.S.C. § 102 rejection is respectfully requested.

The present invention is directed to a solid preparation for dialysis comprising a mixture of (1) a first composition comprising core particles comprising particles of sodium chloride, and a coating layer covering the core particles and containing (a) 0 to 50% by weight of sodium chloride and (b) 100 to 50% by weight of one or more electrolyte selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate, the first composition being granulated into granules having an average particle diameter of 300 to 1,700μm, (2) a second composition comprising core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or a different sugar, the second composition being granulated into granules having an average particle diameter of 300 to 1,700μm, and (3) an acid.

The solid preparation in the present invention corresponds to the first composition in EP '918 and does not contain sodium bicarbonate. The solid preparation of the present invention is mixed with sodium bicarbonate (see, page 14, line 15, to page 15, line 3) to prepare a dialyzate containing sodium bicarbonate (i.e., a blood dialyzate) (see, the composition, page 15, lines 5-18). Therefore, the solid preparation for dialysis of the present invention comprising (1), (2) and (3) is different from the two compositions in EP '918 in which the second composition contains sodium bicarbonate and must be compared with the first composition of EP '918.

Regarding the first composition of EP '918, the Office indicates in the Action that "the first composition contains 2188.7 parts sodium chloride particles with a coating layer of 35.6 part magnesium chloride hexahydrate, 77.2 parts calcium monohydrate [sic] monhydrate, 215.2 parts of sodium acetate trihydrate, and acetic acid with instant sizes (Examples 1-3)." However, in the first composition of Example 1 of EP '918 sodium chloride is neither a core particle nor is it coated with a layer of other electrolytes because 2188.7 part of sodium chloride, 52.2 parts of potassium chloride, 77.2 parts of calcium chloride, 35.6 parts of magnesium chloride and 215.2 parts of sodium acetate are mixed by

stirring, pulverizing and pelletizing in Example 1 and then mixed with acetic acid. Particles of sodium chloride are not coated in Example 1.

The Office also argues that in EP '918, the "examples and claims show that glucose particles are added to the electrolyte composition (page 4 and 8-9)". However, by the dry method disclosed in EP '918, the first composition is obtained by stirring and mixing the solid electrolytes for dialysis and glucose with a stirring and mixing device (page 8, lines 5-11). The glucose is not a core particle and is not a particle coated with a coating layer comprising glucose or a different sugar although the first composition include glucose.

Moreover, the Office has not shown that the glucose particles of EP '918, per se, have a particle diameter of at least 300μm. The position of the Office is that glucose coated with glucose is still glucose. However, the particle diameter of glucose which is commercially available has a particle diameter of 300μm or less (see, for example, Example 1 in the present application in which the glucose particles have a diameter of 180μm). As the first composition (electrolytes) of the solid preparation of the present invention has an average particle diameter of 300 to 1,700μm, the second composition (sugars) should have an average particle

diameter of 300 to 1,700μm to be mixed homogeneously with the first composition in a mixer such as a V-type mixer. As both the first composition and the second composition have similar particle diameters, they are miscible to make a homogeneous mixture which can dissolve quickly into water and show content homogeneity (see, page 11, line 21, to page 12, line 4, of the present application).

On the other hand, if glucose particles are simply added to the electrolyte composition (pages 4 and 8-9, in EP '918), the solid preparation for dialysis by a dry granulation method (as shown in Comparative Example 2 in the present application) will have a non-homogenous content of glucose (see, page 21, Table 1).

The Examiner has noted that in Example 2 in EP '918, sodium chloride is sprayed with an aqueous solution of the instant electrolytes. However, glucose is not included in the electrolytes and thus is not part of the first composition.

As mentioned above, the cited reference, EP '918 neither describes nor suggests that the sugar particles (second composition in the present invention) have a similar particle diameter to that of the electrolytes (first composition in the present invention) to allow the compositions to be homogeneously mixed together. In particular, it is not suggested to separate the glucose from the electrolytes such as sodium chloride, calcium chloride, magnesium

chloride, potassium chloride and sodium acetate, or sodium bicarbonate to prevent decomposition and coloring.

Moreover, applicants note that claims 8 and 9, written in product-by-process terminology, (and the claims dependent thereon) exclude the sodium bicarbonate of the second composition from the solid preparation for dialysis of the present invention.

Claims 8 and 9 recite the step of "spraying, onto core particles comprising particles of a sugar, an aqueous solution of said sugar or a different sugar to obtain second coated particles, and drying the second coated particles to obtain granules of a second composition having an average particle diameter of 300 to 1,700 μm". The term "comprising" recited in the step may leave the step open to core particles other than particles of a sugar, but does not leave the claim open to particles other than core particles. Additionally, the step requires that the core particles be coated with a sugar. If it is assumed for the sake of argument that the core particles could include sodium bicarbonate, the sodium bicarbonate is required to be coated with a sugar that is sprayed thereon. EP '918 does not disclose sodium bicarbonate coated with a sugar.

It is noted that claims 8 and 9 recite the solid preparation for dialysis "as being prepared by a process comprising" certain

specific steps. The term "comprising", when used in a claim to recite method steps, leaves the claim open to other steps, but does not affect the scope of the components recited within the steps. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 [229 USPQ 805] (Fed. Cir. 1986) in which the Federal Circuit rejected as "far too broad" the argument that "comprising" opened the claims to additional steps and additional limitations not contained in the accused method.

For the above reasons, EP '918 cannot anticipate the solid preparation recited in claims 8 and 9 and the claims dependent thereon.

The Office is respectfully requested to consider and address the patentability of claims 8 and 9 and the claims dependent thereon separately from the other claims.

Removal of the 35 U.S.C. § 102 rejection is believed to be in order and is respectfuly solicited.

The foregoing is believed to be a complete and proper response to the Office Action dated October 29, 2003, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

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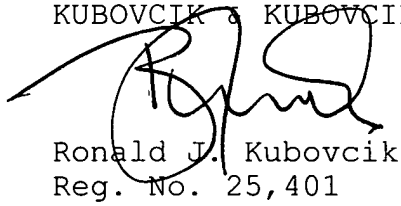

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